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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/443,070	11/18/99	GILTON T	[illegible]

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EXAMINER	
GABEL, J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/443,070	Gilton
Examiner	**Group Art Unit**
Gailene R. Gabel	1641

☒ Responsive to communication(s) filed on *Nov 18, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-29* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior copending Application No. 09/177,814, filed October 23, 1998. A reference to such application is in the first line of the specification; however, the current status of the application is missing.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard

for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also claims 6 and 7.

Claim 1 has insufficient antecedent support in reciting "said porous capillary column".

Claim 1 is unclear in reciting "drawing the sample across a flowfront through said porous capillary column so as to enhance separation of the constituent therefrom" because it is unclear as to what element the constituent is being separated from, i.e. the porous capillary column or the sample.

Claims 3 and 4 are vague and indefinite in reciting "applying a stationary phase" and "effected before (said) applying the sample", respectively, because it is unclear how the separation of the sample is effected by the stationary phase. Specifically, the claims do not define how the separation is effected by the "stationary phase" so as to establish relevancy of such limitations in the claims.

In claim 20, change "said analyze" to --said analyzing-- to correct typographic error.

Claim 20 is vague in reciting "quantifying a change in said detection reagent" because it does not specifically define what is encompassed by the term "change" in the claim, thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claim 22 has improper antecedent basis problem in reciting "**a** stationary phase". Alternatively, claim 22 is inconsistent with claim 18 to which it is dependent upon in reciting "applying a stationary phase" because claim 18 recites "the stationary phase (already) disposed ...

along the capillary column, thereby, effecting its application in the previous claim. See also claim 23.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 1-5, 8-9, 11, 14-16, 18-20, 22-23, and 26-28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Isaka et al. (US 5,482,598).

Isaka et al. disclose a method of separating a sample (fluid), such as gas or liquid, efficiently without requiring a packing material on a chromatograph apparatus. Specifically, Isaka et al. disclose using a chromatography apparatus comprising a microchannel element with a matrix which extends across a semiconductor substrate (see column 1, lines 36-40 and column 2, lines 18-19). The semiconductor substrate comprises of silicon (see column 6, lines 5-7). The matrix is formed with a desired pattern, i.e. linear, circular, on the semiconductor substrate by incorporating a porosity thereon in order to create a porous portion with increased pore size and

extended branching of the pores on the semiconductor surface (see Abstract and column 1, lines 35-46). Isaka et al. disclose applying the sample to a first end of the matrix (injecting a mixture into an inlet port) then drawing the sample across a flowfront through the porous matrix channel from the second end (outlet port) by capillary action. The porous matrix functions as a filter which enhances separation of the desired constituent from the sample (see column 4, lines 16-27). The first end (inlet port) may also be coupled to a pump so that differential pressure can be applied to effect drawing and a solution identified by the difference in flow rate between gases and liquids using a differential refractometer. Separation may involve a capture substrate (immobilized enzyme) wherein separation is on the basis of an affinity of the constituent with the capture substrate in a reaction (absorptivity involving immobilized enzyme) (see column 3, lines 1-14 and 50-54). Isaka et al. specifically teach application of the apparatus in solid-gas separation, solid-liquid separation, liquid-liquid separation, and gaseous separation, i.e. gas chromatography. The length of the matrix channel is not limited although its length is preferably larger than its diameter and the porosity of the matrix is preferably 10-90% (see column 2, lines 18-25 and lines 60-63). Isaka et al. further disclose separation of constituents on the basis of size by suggesting optimizing the pore size and pore shape of the matrix in accordance with the constituent being separated and measured, i.e. selecting the type and concentration of a dopant (see column 3, lines 35-42). Finally, Isaka et al. disclose using an ion column detector on the capillary for detecting presence of the constituent, i.e. absorption detector (see column 3, lines 16-24).

5. Claims 10, 17 and 29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Northrup et al. (US 5,882,496).

Northrup et al. disclose isolation of constituents and filtering of components in a sample using porous silicon structures such as miniaturized electrophoresis devices (see Abstract). Northrup et al. disclose that porous silicon particles have very small pore diameters so that they can be produced with relatively high degree of uniformity and control (see column 1, lines 27-55). In electrophoresis devices, electrodes within or adjacent a porous membrane (capillary column) can be used to draw sample across the flow front and control flow of electrically charged biochemical species (see column 5, lines 21-67). A negative electrode is formed at one end (inlet) of the porous silicon membrane (column) and a positive electrode is formed is formed at an opposite end (outlet) of the porous silicon membrane, thereby forming microelectrophoresis channels (see column 7, lines 38-50). Figure 3 illustrates porous silicon embodiment on a controlled flow interface device. Figure 8 illustrates a porous silicon electrophoresis device. Northrup et al. teach that because of its high surface area and specific pore size, porous silicon can be utilized for a variety of applications on a miniature scale for significantly augmenting adsorption, vaporization, desorption, condensation, and flow of liquids and gasses while maintaining the capability of modification such as being doped or coated using conventional integrated circuit and micromachining (see Summary).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 12-13, 21, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Sunzeri (US 5,536,382) and Swedberg et al. (US 5,571,410).

Isaka et al. has been discussed supra. Isaka et al. fail to teach use of internal reference or control. Isaka et al. further fail to teach biocompatible porous medium of particles incorporated into the stationary phase such as antigens antibodies for use as capture system.

Sunzeri discloses analysis of constituents of human biological fluids using capillary electrophoresis. Sunzeri specifically teaches the use of standard control to provide a standard for quantitation (see column 9, lines 28-67). Sunzeri further teaches that quantitation using internal and external standards is beneficial in assays where the sample matrix affects fluorescence sample quenching (see column 10, lines 1-34).

Swedberg et al. teach a miniaturized planar column device for integrated sample analysis of analytes (see column 8, lines 5-38). Swedberg et al. specifically teach a stationary phase (sample treatment component) which performs a filtration function filled with a biocompatible porous medium of particles into which a capture function has been incorporated therein (see

column 27, lines 33-61 and Example 1). Swedberg et al. also disclose a "LIGA" process which is used to refer to a process of fabricating microstructures having high aspect ratios and increased structural precision in order to create desired uniformity in microstructures such as channels ports, apertures, and microalignment means (see column 13, lines 9-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stationary phase of the chromatographic separation apparatus taught by Isaka with one that effects biocompatibility into the matrix, i.e. antigens and antibodies, as taught by Swedberg in order to achieve simultaneous performance of separation, filtration, and capture function using a single chromatographic device because Swedberg specifically suggested potential application of his teachings in monitoring biological analyses as applied to liquid phase separation devices in the miniature scales. One of ordinary skill in the art would have been motivated to incorporate the teachings of Isaka with biocompatible modification as taught by Swedberg because Isaka specifically taught that porous silicon has established porosity with enhanced capacity for separation, augmented adsorption, differentiation of flow rate in liquid or gaseous samples, thereby producing a highly versatile miniaturized chromatographic device capable of both enhanced partitioning and complexation reactions. Furthermore, with the advent of silicon micromachining and LIGA in the teachings of Swedberg, one of ordinary skill in the art would have reasonable expectation of success in fabricating multiple separation columns or channels with a high degree of uniformity and precision in order to allow accurate comparative and correlative measurement of sample results in comparison to internal controls, references, or

standards with known measurement levels as those taught by Sunzeri, because quality control monitoring is a standard practice and a well known art for monitoring the functionality, accuracy, and precision of various laboratory apparati.

7. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Yu (US 5,583,281).

Isaka et al. has been discussed supra. Isaka et al. fail to disclose a capillary column which specifically uses inert gas in the mobile phase.

Yu discloses a miniature gas chromatograph comprising a silicon wafer, a gas injector, a column and a detector. The column is a microcapillary in silicon crystal with a stationary phase and is mechanically connected to receive a mobile phase from the gas injector for molecular separation of compounds in a sample gas (see Abstract). The mobile phase is a carrier gas or inert gas, usually nitrogen, hydrogen, helium, or argon (see column 2, lines 28-42).

One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using inert gases such as taught by Yu in the column chromatograph of Isaka because use of such carrier gases is conventional and well-known in the art of gas chromatography.

8. For reasons aforementioned, no claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

5/18/02

Gailene R. Gabel
Patent Examiner
Art Unit 1641